Application No.: 10/551,579 Docket No.: 532552000701

CLAIM AMENDMENTS

1-32. (canceled)

33. (currently amended): A method to deliver a <u>synergistic</u> therapeutically effective amount of a fluoropyrimidine/water-soluble camptothecin drug combination [[by]] to a <u>subject</u> which method comprises administering to said <u>subject</u> a first composition containing a fluoropyrimidine stably associated with a first <u>particulate</u> delivery vehicle and <u>a second composition</u> containing a water-soluble camptothecin stably associated with a second <u>particulate</u> delivery vehicle wherein the ratio of the fluoropyrimidine and the water-soluble camptothecin administered is non-antagonistic,

wherein said stable association maintains, for at least one hour, a synergistic ratio of said fluoropyrimidine and camptothecin in the blood when administered *in vivo*, and

wherein said synergistic ratio is such that when said ratio is provided to cancer cells in an *in vitro* assay over the concentration range at which the fraction of affected cells is 0.20 to 1.00, synergy is exhibited over at least 20% of said range.

- 34. (new): The method of claim 33 wherein the particulate delivery vehicles have a mean diameter of between 4.5 and 500 nm.
 - 35. (new): The method of claim 33 wherein said delivery vehicles comprise liposomes, and/or lipid micelles, and/or block copolymer micelles, and/or microparticles, and/or nanoparticles, and/or polymer lipid hybrid systems, and/or derivatized single chain polymers.

sd-399133 2

Application No.: 10/551,579 Docket No.: 532552000701

36. (new): The method of claim 33 wherein the water-soluble camptothecin is irinotecan (CPT-11), topotecan, 9-aminocamptothecin or lurtotecan.

- 37. (new): The method of claim 33 wherein the water-soluble camptothecin is a hydrophilic salt of a water-insoluble camptothecin.
- 38. (new): The method of claim 33 wherein the water-soluble camptothecin is irinotecan (CPT-11) or topotecan.
- 39. (new): The method of claim 33 wherein the fluoropyrimidine is floxuridine, fluorouracil or UFT (tegafur/uracil).
- 40. (new): The method of claim 33 wherein the water-soluble camptothecin is irinotecan and said fluoropyrimidine is floxuridine or 5-FU.
 - 41. (new): The method of claim 40 wherein the ratio is 1:1.
- 42. (new): The method of claim 33 which further comprises administering leucovorin to said subject.
- 43. (new): A kit that comprises a first container containing the first composition_and a second container containing the second composition as described in claim 33.
- 44. (new): The kit of claim 43 wherein the amounts of said first and second compositions in each container are premeasured to provide a synergistic ratio.

sd-399133 3